GOVERNMENT OF INDIA
COMMERCE AND INDUSTRY
LOK SABHA

UNSTARRED QUESTION NO:2332
ANSWERED ON:01.08.2016
Export of Pharmaceutical Products
Butta Smt. Renuka;Godse Shri Hemant Tukaram

Will the Minister of COMMERCE AND INDUSTRY be pleased to state:

(a) whether the Government proposes to boost the exports of pharmaceutical products and if so, the details thereof along with the steps taken in this regard;
(b) the details of the pharmaceutical products exported and the foreign exchange earned therefrom during the last three years and the current year, country-wise;
(c) whether the Government proposes to issue new regulations for the export of pharmaceutical products;
(d) if so, the details thereof along with the extent to which the proposed regulations are likely to impact the volume of exports from the country and counter the adverse campaign against the quality of Indian drugs in foreign countries;
(e) whether the Government has made barcoding mandatory for exports including pharma exports and if so, the details thereof; and
(f) whether the Government has received any representation from Indian Pharmaceutical Industry to exempt Small Scale Industries from barcoding for exports and if so, the details thereof along with the response of the Government thereto?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF COMMERCE AND INDUSTRY (INDEPENDENT CHARGE)
(SMT. NIRMALA SITHARAMAN)

(a) :The Government is taking several measures to boost exports. Financial assistance is provided under Market Development Assistance and Market Access Initiative Schemes by Department of Commerce to exporters of various Pharmaceutical products particularly small and medium size exporters to promote their exports in various countries. Incentives to Pharmaceutical industry are also available in various trade promotion schemes like Merchandise Exports from India Scheme (MEIS), Advance Authorization Scheme, DFIA (Duty Free Import Authorization) for import of raw materials and Export Promotion Capital Goods (EPCG) Scheme for import of Capital Goods etc.

(b) :The details of pharmaceutical products exported and the foreign exchange earned there from during the last three years and the current year are enclosed at Annexure-I & II respectively :

(c) & (d) : Currently, there is no such proposal to issue new regulations for the export of pharmaceutical products. For export of drugs, Indian Pharmaceutical companies are required to comply with the regulatory provisions of the importing country.

(e) & (f) : Bar coding has been made mandatory only for the pharmaceutical exports (Formulations) and not for other product categories. Manufacturer or exporter of drug formulations will print the bar code as per GSI Global Standard at different packaging levels VIL secondary & tertiary to facilitate tracking and tracing of their products as per the procedure prescribed vide DGFT Public Notice No.52/2015-2020 dated 5th January 2016 (copy enclosed at Annexure-III). This is to ensure that counterfeit or spurious drugs are not sold under "Made in India" label or/and any such allegations is traceable. Some manufacturers and exporters especially the small scale units have been representing to Department of Commerce that they would require extended time period for implementation of the track and tracing system. After careful consideration of the representations and in consultation with various stakeholders, vide DGFT Public Notice No 52/2015-2020 dated 5/1/2016, Government has exempted all SSI drug manufacturers from the requirement of maintaining Parent Child relationship in packaging levels for a period up to 31/03/2017.
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Annex-I
India"s Exports in $ mn
Category 2013-14 2014-15 2015-16 2016-17
April & May)
Ayush 159 118 109 40.24
Bulk drugs 3598 3565 3585 557.81
Formulations 10670 11214 12646 2046.67
Herbal Products 206 236 250 18.06
surgicals 302 299 300 51.61
Grand Total 14935 15433 16889 2714.40

Annexure - II
Exports to Top 30 Countries in $ mn Export to Top 30 countries APRIL,2016 - MAY,2016
Rank Country 2013-14 2014-15 2015-16 Gr% Rank COUNTRY APRIL,2016 - MAY,2016 Gr%
1 U S A 3963 4310 5503 27.69 1 U S A 939.99 -15.6458

2 SOUTH AFRICA 561 511 607 18.67 2 U K 97.06 17.86
3 U K 527 543 564 3.88 3 RUSSIA 64.50 1.27
4 NIGERIA 384 421 437 3.98 4 GERMANY 58.32 2.25
5 RUSSIA 546 425 374 -11.95 5 NIGERIA 55.58 -10.30
6 GERMANY 402 373 348 -6.75 6 SOUTH AFRICA 54.38 -33.35
7 KENYA 240 284 333 17.24 7 BRAZIL 54.36 -0.49
8 BRAZIL 313 376 325 -13.55 8 KENYA 53.56 5.44
9 NETHERLAND 234 243 243 0.00 9 GHANA 44.75 113.98
10 AUSTRALIA 197 206 233 13.12 10 AUSTRALIA 36.89 2.33
11 FRANCE 207 209 232 11.08 11 SRI LANKA DSR 36.58 14.06
12 VIETNAM SOC REP 212 233 221 -5.23 12 NEPAL 36.07 29.35
13 SRI LANKA DSR 167 173 205 18.47 13 VIETNAM SOC REP 35.43 4.74
14 CANADA 227 208 201 -3.42 14 CANADA 34.95 -5.99
15 PHILIPPINES 140 156 193 23.88 15 NETHERLAND 34.26 -20.87
16 BELGIUM 128 154 192 24.77 16 BELGIUM 32.86 -13.60
17 IRAN 183 175 180 2.71 17 PHILIPPINES 31.53 27.82
18 TANZANIA REP 157 187 179 -4.76 18 FRANCE 31.00 -10.33
19 NEPAL 142 169 170 0.57 19 MEXICO 28.52 -14.63
20 UGANDA 155 158 169 6.94 20 EGYPT A RP 28.17 -20.17
21 EGYPT A RP 93 117 162 38.39 21 ETHIOPIA 27.93 106.85
22 MEXICO 125 127 160 26.54 22 TURKEY 26.22 5.62
23 TURKEY 156 148 160 8.22 23 BANGLADESH PR 26.15 -2.35
24 MYANMAR 139 173 154 -10.50 24 UGANDA 24.79 -3.30
25 THAILAND 109 157 148 -6.14 25 CHINA P RP 22.98 -27.63
26 JAPAN 175 142 144 1.15 26 SPAIN 22.45 3.88
27 ETHIOPIA 146 125 140 12.52 27 MOZAMBIQUE 21.79 268.03
28 CHINA P RP 116 139 140 0.58 28 JAPAN 21.61 4.62
29 GHANA 152 165 138 -16.17 29 IRAN 21.20 -55.80
30 BANGLADESH PR 158 141 136 -3.54 30 SINGAPORE 20.27 3.43
Total of The above 10457 10949 12393 13.19 Total of the above 2024.13 -8.10
Grand Total 14935 15433 16889 9.44 Grand Total 2714.00 -7.00

Annexure-III

To be published in the Gazette of India Extraordinary Part-I, Section-I
Government of India
Ministry of Commerce and Industry
Department of Commerce
Directorate General of Foreign Trade

Public Notice No. 52/2015-2020
New Delhi, Dated the 5 January,2016

Subject: Implementation of the Track and Trace system for export of Pharmaceuticals and drug consignments.

In exercise of the powers conferred under Paragraph 2.04 of the Foreign Trade Policy, 2015-20, as amended from time to time, the Director General of Foreign Trade hereby amends Para 2.89A of Handbook of Procedure, 2015-20, as notified vide Public Notice No. 4/2015-20 dated I .04.2015 (as amended), as under, for laying down the procedure for implementation of the Track and Trace system for export consignments of drug formulations:
2. "2.89 A
Procedure for Implementation of the Track and Trace system for export of drug formulations
i. The manufacturer or the exporter of drug formulations will print the barcode as per GSI Global Standard at different packaging levels to facilitate tracking and tracing of their products. The details are as follows:

a) Primary Level:

Incorporation of two dimensional (2D) barcode encoding unique and universal global product identification code in the format of 14 digits Global Trade Item Number (GTIN) along with batch number, expiry date and a unique serial number of the primary pack. The bar code labeling at primary level is exempted till further notification; however, the above mentioned details are required to be printed in human readable form on optional basis till further notification.

b) Secondary level:
Incorporation of one or two dimensional (1D or 2D) barcode encoding unique and universal global product identification code in the format of 14 digits Global Trade Item Number(GTN) along with batch number, expiry date and a unique serial number of the secondary pack. However, incase of monocartons manufacturer or exporter shall affix bar code on mono carton containing one primary pack on optional basis till further notification.

c) Tertiary Level:
Incorporation of one dimensional (1D) barcode encoding unique and universal global product identification code in the format of 14 digits Global Trade Item Number (GTIN) along with batch number, expiry date and a unique serial number of the tertiary pack i.e. Serial Shipping Container Code (SSCC).

ii) Parent -Child Relationship/ Effective dates for SSI and Non-SSI Manufacturers:

The manufacturer or exporter shall maintain the data in the parent-child relationship for three levels of packaging i.e. Primary, Secondary and Tertiary packaging and their movement in its supply chain.

a) All Manufacturers (SSI & Non- SSI Manufacturers):

As one time exemption all manufacturers are exempted from maintenance of parent-child relationship in packaging and its uploading on central portal (http://dava.gov.in) till 31.03.2016. However, the requirements of printing of barcoding on the different levels or packaging will be applicable as prescribed.

b) Extended Date of Exemption to SSI Manufacturers:

All SSI drug manufacturers are exempted from requirement of maintaining Parent-Child relationship in packaging levels for a further period up to 31.03.2017. However, they are required to upload Tertiary level data on the central portal mandatorily as prescribed in public notice no. 13/2015-2020 dated 22.05.2015.

iii) The data mentioned in (ii) above shall be uploaded on the central portal of the Government of India by the manufacturer or exporter or its designated agency before release of the drug formulations for sale or distribution.
iv) The responsibility of the correctness, completeness and ensuring timely upload of data on the central portal shall be with the manufacturer or exporter"
v) The above rules (i) to (iv) will not be applicable to those drug formulations manufactured for export purposes, where the government of the importing country has mandated or formally notified its intention to mandate a specific requirement and the exporter intends to avail the option of printing the barcodes in their format after duly obtaining the permission of DCGI or its nominee. However, the tertiary level of packaging will have additional printing of barcode as per (i)(c) above in addition to importing country"s requirement, if any.
vi) Export of drugs manufactured by non-SSI units and having manufacturing date prior to 31.03.2016 and export of the drugs manufactured by SSI units and having manufacturing date prior to 31.03.2017 are exempted from requirement of data uploading on Central Portal.
vii) All drugs manufactured by non SSI units with manufacturing date on or after 01.04.2016 and all drug manufactured by SSI units with manufacturing date on or after 01 .04.2017 can be exported only if both tertiary and secondary packaging carry barcoding as applicable and the relevant data as prescribed by DGFT is uploaded on the Central Portal.

Explanation:

(a) For the purpose of this rule,

(i) Drug formulation means a formulation manufactured with a license from Drug Control Authority under the provisions of Drugs & Cosmetics Act and Rules made there under and registered as "Drug" with the FDA of importing country.

(ii) Primary packaging means the package which is in direct physical contact with the active ingredient.

Secondary packaging means a carton containing one or more primary packs and includes a mono carton containing one primary pack.

The tertiary packaging means a shipper containing one or more secondary packs.

(b) All relevant guidelines regarding grant of specific exemption (s) if any, procedure of data requirement / maintenance / upload on central portal and clarifications issued under this notification etc. will be available on the central portal i.e. http://dava.gov.in

(c) It will be the responsibility of the drug manufactures/exporters as the case may be, to satisfy the customs authorities that the export consignment satisfies the conditions of the notification".

3. Effect of this Public Notice:

In suppression of the earlier Public Notice no. l3/2015-2020 dated 22.05.2015, the dates for implementation of Track and Trace system for export of drug formulations alongwith maintaining the Parent-Child relationship in packaging have been extended to 01.04.2016 for non SSI manufactured drugs and to 01.04.2017 for SSI manufactured drugs.
Sd/-
(Anup Wadhawan)
Director General of Foreign Trade
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(Issued from F.No. 01/91/180/648/AM 09/Export Cell)